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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,091	02/02/2004	Richard A. Hamer	FLI-14402/03	9264
25006	7590	03/22/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C			WARE, DEBORAH K	
PO BOX 7021			ART UNIT	
TROY, MI 48007-7021			PAPER NUMBER	

1651

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,091	HAMER ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are pending.

Information Disclosure Statement

The information disclosure statement (IDS)s submitted on April 20, 2004 and October 6, 2004, were received. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method for treating a microbe, classified in class 435, subclass 243.
- II. Claims 11-19, drawn to therapeutic material, classified in class 424, subclass 400.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown:

(1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case the product as claimed can be used in a materially different process, such as in a method for cleaning medicinal supplies or for treating environmental equipment (i.e. cistern).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Citkowski on March 13, 2006, a provisional election was made **without** traverse to prosecute the invention of I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 5-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Carpenter et al (US 5356803), cited on enclosed PTO-1449 Form.

Claims are drawn to a method for treating a microbe mediated dermatological condition in an organism, comprising treating an affected tissue of said organism with

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an agent that is capable of disrupting a microbial biofilm. Galactosidase can be the agent and further the treatment can include a step comprising treating with an antimicrobial compound.

Carpenter et al teach a method for treating a microbe mediated dermatological condition in an organism, comprising treating an affected tissue of said organism with an agent that is capable of disrupting a microbial biofilm. Surfaces to be treated include biofilms, note col. 14, line 4. At col. 10, line 65, galactosidase is disclosed as a critical treatment agent. The method is disclosed to be practiced on a living organism, note col. 10, lines 27-30. The composition of the disclosed method includes anti-acne compositions and surfaces to be treated include skin, note col. 19, lines 26 and 45. The galatocidases can be used alone and/or in combination with a different component comprising antimicrobial compounds, note col. 3, lines 49-53.

The claims are identical to the cited disclosure, and are therefore, considered to be clearly anticipated by therein.

Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al (US 5,320,805), cited on enclosed PTO-892 Form.

Claims are discussed above and are further drawn to an agent being selected from not only peroxide radicals, but can be sonic waves.

Kramer et al teach a method for treating an affected tissue with an agent such as sonic waves and/or peroxide radicals, note col. 7, lines 35-36 and col. 13, lines 40-42, wherein biofilms are disrupted as a result of destroying or killing off the microbes making up the biofilms. Skin is treatable as noted at col. 2, line 23.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings therein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Crisp et al (US 6522918), cited on enclosed PTO-892 Form.

Claims are discussed above and are further drawn to an agent comprising an electrical field.

Crisp et al teach treating skin on the body with an electrical field to promote healing action for medicinal and hygienic purposes and that electrical fields can exert a microbiocidal effect on tissues such as biofilms and hence disrupt them, note col. 1, lines 15-26.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings therein.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 5-10 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burrell et al (US 6939568), cited on enclosed PTO-892 Form.

Claims are discussed above and further are drawn to treating tissue comprising nail tissue and a dermatological condition comprising dermatophytoma.

Burrell et al teach a method for treating a microbe mediated dermatological condition in an organism, such as dermatophytoma of nail tissue, note col. 3, lines 46-

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68, comprising treating an affected nail tissue of said organism with an agent, such as peroxide radicals (i.e. benzoyl peroxide), note col. 5, line 34. Acne of the skin can also be treated, note col. 4, line 14. Further, another antimicrobial metals are used as well, note the abstract, lines 1-2.

The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by therein. The microbial biofilm is inherent to the cited disclosure because the inflammatory dermatological conditions of the skin are taught to be caused by microbial colonies of which are well known in the art to be comprised by biofilms.

However, in the alternative that there is some difference between the cited disclosure and claimed invention then such difference is considered to be so slight as to render the claims obvious over the cited reference in the alternative, thereof. It would have been obvious to one of ordinary skill in the art to disrupt a microbial biofilm to treat the dermatological condition as disclosed by Burrell et al.

One of skill would have been motivated by the teachings therein for treating a microbe mediated dermatological condition in an organism comprising treating an affected tissue of the organism with an agent, like peroxide radicals, to disrupt bacterial growth whether in the form of an infection or in a microbial biofilm. Clearly one of skill would have expected successful results. To add an antimicrobial compound simultaneously or after the treating agent is clearly an obvious modification of the cited prior art. Acne is clearly disclosed to be treatable as is dermatophytoma of the skin and nail tissue. The claims are in the alternative rendered prima facie obvious over the cited prior art.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter et al (US 5356803), cited above in view of Burrell et al (US 6939568), cited above as well.

Claim 10 is drawn to the method comprising affected tissue that is nail tissue and a condition comprising dermatophytoma.

Carpenter et al and Burrell et al are both discussed above.

The claim differs from Carpenter et al in that nail tissue and dermatophytoma are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Carpenter et al and Burrell et al to provide for a method for treating dermatophytoma wherein the affected area is nail tissue with the disruption of a biofilm as disclosed by the cited prior art combination. To disrupt the biofilm disclosed by Carpenter et al by treating nail tissue would have been clearly expected to successfully treat dermatophytoma because the prior art recognizes that the agents disclosed by Carpenter et al and Burrell et al have been successful for treating a microbe mediated dermatological condition in an organism. Thus, one of skill would have expected successful results. In the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.


The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
March 16, 2006